

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LYNN OXENBERG and RONALD LEWIS

*Plaintiffs,*

v.

Civil Action No. 20-738-CMR

ALEX M. AZAR II, in his official capacity  
as Secretary of the United States Department  
of Health and Human Services,

*Defendant.*

**THE DEFENDANT'S REPLY  
IN SUPPORT OF RULE 12(B)(1) MOTION TO DISMISS**

WILLIAM M. McSWAIN  
United States Attorney

ERIC S. WOLFISH  
Special Assistant United States Attorney  
United States Department of Health  
and Human Services  
Office of the General Counsel, Region III  
801 Market Street, Suite 9700  
Philadelphia, PA 19107-3134  
(215) 861-4511  
eric.wolfish@hhs.gov

*Counsel for the defendant*

MATTHEW E. K. HOWATT  
Assistant United States Attorney  
United States Attorney's Office  
615 Chestnut Street, Suite 1250  
Philadelphia, PA 19106  
(215) 861-8335  
matthew.howatt@usdoj.gov

## I. INTRODUCTION

In three virtually identical TTFT cases litigated by the plaintiffs’ national counsel, three different district court judges have recently dismissed for lack of Article III standing. In the plaintiffs’ opposition to the motion to dismiss this case, the plaintiffs note that two of those decisions are on appeal, but they do not explain why the district courts’ reasoning was wrong. *See* Dkt. No. 34 at 14-15 (“P. Opp.”). Each of those decisions rejected essentially the same arguments that the plaintiffs present here. In particular, those courts found that a claim denial, absent any responsibility to pay for treatment, does not constitute an injury in fact. Those courts also found that the plaintiffs’ speculation that they may become personally liable for future treatments is too speculative to establish standing.<sup>1</sup> This Court should follow those three analogous cases and dismiss this case.

In addition to this highly persuasive authority, both U.S. Supreme Court and Third Circuit law mandate dismissal for lack of standing. It remains undisputed that, no matter the outcome, the plaintiffs have no financial responsibility related to the claims on appeal. Absent any concrete injury, the plaintiffs assert they have a substantive “right” to require Medicare, rather than Novocure, to bear the cost of their claims. However, no such right exists under the Medicare statute, and the Third Circuit has held that a plaintiff lacks standing to shift the costs of medical claims from one party to another because such a plaintiff “never has had anything to gain from [the] lawsuit.” *Wheeler v. Travelers Ins. Co.*, 22 F.3d 534, 538 (3d Cir. 1994). The Supreme Court likewise holds that a plaintiff has no concrete stake in a lawsuit where the outcome will not affect the amount of a benefit payment. *Thole v. U.S. Bank N.A.*, 140 S.Ct.

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<sup>1</sup> *Pehoviack v. Azar*, 2020 WL 4810961, at \*3 (C.D. Cal. July 22, 2020); *Komatsu v. Azar*, 2020 WL 5814116, at \*3 (C.D. Cal. Sept. 24, 2020); *Prosser v. Azar*, 2020 WL 6266040, at \*1 (E.D. Wis. Oct. 21, 2020).

1615, 1618-19 (2020).

Because the plaintiffs’ alleged injury is, at most, a “bare procedural violation, divorced from any concrete harm” that does not satisfy the requirements for Article III standing, their complaint should be dismissed. *Spokeo, Inc. v. Robins*, 136 S.Ct. 1540, 1549 (2016).

## **II. ARGUMENT**

### **A. The Plaintiffs Have Not Suffered an Injury in Fact.**

In *Bognet v. Sec. Commonwealth of Pa.*, --- F.3d ---, No. 20-3214, 2020 WL 6686120 (3d Cir. Nov. 13, 2020), the Third Circuit recently explained the plain meaning of the standing doctrine:

To bring suit, you—and you personally—must be injured, and you must be injured in a way that concretely impacts your own protected legal interests. *If you are complaining about something that does not harm you—and does not harm you in a way that is concrete—then you lack standing.* And if the injury that you claim is an injury that does no specific harm to you, or if it depends on a harm that may never happen, then you lack an injury for which you may seek relief from a federal court.

*Id.* at \*6 (emphasis added). That describes this case as well. As discussed further below, the plaintiffs disagree with Medicare’s denial of their claims, but fail to identify any injury they have suffered. Because their alleged future injury may never happen, they lack standing.

#### **1. The plaintiffs have not alleged a past injury in fact.**

##### **a. It is undisputed that plaintiffs do not allege a tangible injury.**

A “paradigmatic form[]” of injury in fact is economic injury. *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (Alito, J.). “Standing always should exist to claim damages, unless perhaps the theory of damages is totally fanciful.” *Id.* (quotation marks omitted). In this case, however, the plaintiffs have not suffered any economic injury. It is undisputed that the ALJs found that the plaintiffs have no financial responsibility for the claims at issue. *See* Dkt. No. 31 (“D. MTD”) at 3-4. It is also undisputed that, no matter the outcome of

this case, Novocure cannot hold the plaintiffs financially responsible for the claims. *Id.* at 2.

**b. Plaintiffs have not established a substantive statutory violation.**

Absent any tangible injury, the plaintiffs assert a deprivation of their alleged substantive, intangible “entitlement” to Medicare benefits. Merely asserting that their Medicare claims were wrongly decided, however, does not suffice for standing. “Article III standing requires a concrete injury even in the context of a statutory violation.” *Spokeo*, 136 S.Ct. at 1549; *see also Kamal v. J. Crew Group*, 918 F.3d 102, 113 (3d Cir. 2019) (“If the violation does not present a ‘material risk of harm to that underlying interest,’ however, a plaintiff fails to demonstrate concrete injury.”) (citing *Spokeo*, 136 S. Ct. at 1549). Accordingly, two elements must be present for a statutory violation to constitute a cognizable injury: (1) Congress must have determined that the statutory violation is a sufficient injury to satisfy Article III; and (2) the harm must have “long been seen as injurious” under the common law. *See Spokeo*, 136 S.Ct. at 1549; *Kamal*, 918 F.3d at 111-15; *Thorne v. Pep Boys Manny Moe & Jack Inc.*, --- F.3d. ---, No. 20-1540, 2020 WL 6814573, at \*7 (3d Cir. Nov. 20, 2020). Neither element is present here.

First, Plaintiffs allege a denial of their “Congressionally created entitlement to Medicare coverage,” P. Opp. at 5, but the statutes they cite do not identify a statutory violation that is a sufficient injury to satisfy Article III. The only Medicare-related statute that plaintiffs have sued under is 42 U.S.C. § 405(g), which authorizes judicial review of a final decision of the Commissioner of Social Security made after a hearing. Dkt. No. 1 (Complaint) at 8. The review procedures in section 405(g) are made applicable to the Secretary by 42 U.S.C. § 1395ii. Neither section 405(g) nor section 1395ii refer to Medicare benefits, and, indeed, the review procedures in section 405(g) apply to a wide ambit of cases arising under the Social Security Act, such as disability and Supplemental Security Income cases. *See* 42 U.S.C. § 405(h); *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 10, 14 (2000) (noting that section 405(h) extends

to “claims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy”). Meanwhile, section 405(g) does not entitle a claimant to any particular benefit. Instead, section 405(g) authorizes a court to affirm, modify, or reverse the Secretary’s decision, with or without remanding for a hearing. In sum, section 405(g) merely provides a procedural vehicle that may—or may not—lead to a claimant receiving some benefit or recourse under a separate law or regulation. *See, e.g., Cal. Clinical Lab. Ass’n v. Sec. of HHS*, 104 F. Supp. 3d 66, 76-78 (D.D.C. 2015) (finding that the statutorily conferred right to file an local coverage determination challenge was insufficient for standing, because it was procedural and merely a “means to achieve the ultimate end the recipients seek.”).<sup>2</sup>

The plaintiffs cite various other Medicare provisions, which are inconsequential because the Complaint does not allege that the Secretary violated them. Nor do any of the statutes the plaintiffs cite entitle them to have Medicare pay for their TTFT claims. In particular, 42 U.S.C. § 1395ff(a)(1) authorizes the Secretary to “promulgate regulations and make initial determinations with respect to benefits” concerning “[t]he initial determination of whether an individual is entitled to benefits” as well as “[a]ny other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made.” *Id.* Accordingly, this statute is consistent with the Secretary’s broad authority to determine whether to approve claims for benefits. Meanwhile, 42 U.S.C. § 1395k(a)(1) contains definitions of the broad categories of medical and other services that are eligible for Medicare coverage. Likewise, the Third Circuit’s description of Medicare as a “federal entitlement program that provides health insurance benefits to qualified

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<sup>2</sup> Plaintiffs do not attempt to distinguish this aspect of the *California Clinical* decision. *See* P. Opp. at 13-14.

elderly and disabled individuals” merely describes the population that is eligible for Medicare. *Taransky v. Sec. of U.S. Dept. Health & Human Servs.*, 760 F.3d 307, 310 (3rd Cir. 2014).

The plaintiffs’ reliance on the Supreme Court’s decision in *Heckler v. Ringer* is also misplaced. 466 U.S. 602 (1984). *Ringer* did not analyze Article III standing, but rather discussed claims “arising under” the Medicare Act and the limitations on federal question jurisdiction. *Id.* at 620. A respondent alleged that the Secretary’s refusal to allow payment precluded him from having an operation. The mid-sentence-spliced quotation from the plaintiffs’ opposition brief comes from this full context:

As to § 1331 jurisdiction, as with the other three respondents, all aspects of [respondent’s] claim “aris[e] under” the Medicare Act in that the Medicare Act provides both the substance and the standing for [respondent’s] claim, *Weinberger v. Salfi*, 422 U.S., at 760–761, 95 S.Ct., at 2464–2465. Thus, consistent with our decision with respect to the other three respondents, we hold that §§ 1331 and 1361 are not available as jurisdictional bases for vindicating [respondent’s] claim.

*Id.* at 620-21. Far from concluding that any statutory violation of the Medicare Act is substantive in nature, the Court merely found that respondent’s claim for payment arose under the Medicare Act (and not under other jurisdictional bases).

The plaintiffs also cite several district court decisions finding standing where Medicaid paid claims that were denied by Medicare. P. Opp. at 5-6. However, the *Martinez* (D.N.M. 1986) and *Longobardi* (D. Conn. 1988) decisions are “inconsistent with modern standing precedent of the Supreme Court because they rely on a notion that standing may be founded on no more than an abstract ‘entitlement’ right created by statute without focus on whether a plaintiff has sustained a practical, concrete injury from the claimed violation of the statutory right.” *Hull v. Burwell*, 66 F. Supp. 3d 278, 284 (D. Conn. 2014). *Anderson* (D. Vt. 2010) is also faulty as it relied on *Longobardi*. These decisions, which are inconsistent with and pre-date the relevant Supreme Court and Third Circuit precedent

discussed above, are not persuasive.<sup>3</sup> Moreover, as addressed below, *Ryan* (D. Vt. 2015) and these other decisions are also distinguishable to the extent they rely on the incorrect argument that the plaintiffs here would lose their “mulligan.” *See infra*, pp. 7-10.

Meanwhile, the plaintiffs do not dispute that the ALJs’ determination that Novocure was responsible for the cost of their claims was consistent with the applicable Medicare statute and regulation. Citing 42 U.S.C. § 1395pp and 42 C.F.R. § 411.406(e), the ALJs determined that Novocure was responsible for knowing that the disputed TTFT services were not medically reasonable and necessary. AR at 109, 839.

In sum, the plaintiffs have not alleged a violation of a Medicare statute that entitled them to Medicare coverage, much less a congressional determination that the statutory violation is a sufficient injury to satisfy Article III. No statute guarantees that any particular claim by a Medicare beneficiary will be covered, and no statute identifies what injury a beneficiary paying nothing out-of-pocket has suffered. The plaintiffs have not shown a congressional determination that “elevated” the denial of a Medicare claim for a beneficiary who lacks financial responsibility into “an injury that is concrete for Article III purposes.” *See Thorne*, 2020 WL 6814573, at \*9.

Even if the plaintiffs had shown an entitlement to Medicare benefits (which they have not), they make no attempt to argue that their alleged statutory injury has “long been seen as injurious” under the common law. *See Thorne*, 2020 WL 6814573, at \*7 (evaluating whether there is a “historical analogue that could remedy the alleged harm”). The plaintiffs allege that they have been deprived of their purported right to insist that Medicare, rather than Novocure, bear the expense of their claims. P. Opp. at 7. Economically speaking, however, it makes no

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<sup>3</sup> The plaintiffs’ citation to *Ross v. Bank of America, N.A. (USA)*, 524 F.3d 217, 222 (2d Cir. 2008) is inapposite, because the court was addressing standing where a defendant’s actions caused both injuries and benefits. *See* P. Opp. at 6. Here, there was no concrete injury.

difference to the plaintiffs which third party bears the cost of their claims. The plaintiffs' mere preference for Medicare to bear the cost does not set forth a common law injury. As in *Wheeler*, the plaintiffs lack standing to insist that the party of their choosing bear the cost of their claims, because they "never [] had anything to gain from this lawsuit." 22 F.3d at 538; D. MTD at 8-9.<sup>4</sup> And as in *Koons*, the plaintiffs "no longer ha[ve] anything personally to gain" from arguing that Medicare, rather than Novocure, should be financially responsible for paying her claim. *Koons v. XL Ins. Am., Inc.*, 620 F. App'x 110, 112-13 (3d Cir. 2015).<sup>5</sup>

The plaintiffs also fail to meaningfully distinguish *Thole*, in which plaintiffs alleged a statutory injury based on alleged mismanagement of a pension plan. Likewise, the plaintiffs allege a statutory injury based on the denial of their Medicare claims. 140 S.Ct. at 1618-19. In both cases, the outcome of the lawsuit had no financial impact on the litigants. Contrary to the plaintiffs' assertion, the outcome of this suit will not affect whether the plaintiffs themselves "receive their payment for their treatments by Medicare." P. Opp. at 7. The ALJs determined that the plaintiffs are not financially responsible for the claims on appeal. If the plaintiffs win this appeal, Medicare will bear the cost of their claims; if the plaintiffs lose, Novocure will bear the cost of their claims. Win or lose, the plaintiffs have no "concrete stake in this lawsuit" and therefore lack Article III standing. *Thole*, 140 S.Ct. at 1619.

## **2. The plaintiffs have not shown a future injury giving rise to standing.**

The plaintiffs assert that, if their claim denials are not reversed, they might lose their

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<sup>4</sup> The plaintiffs attempt to distinguish *Wheeler* on grounds unrelated to their failure to allege a common-law-type injury. P. Opp. at 12-13. The plaintiffs' attempt to distinguish *Wheeler* also erroneously assumes that they have a "substantive statutory right" to have Medicare pay their benefits and have lost their "mulligan."

<sup>5</sup> Although the plaintiffs note that *Koons* is not a Medicare case, that distinction makes no meaningful difference. P. Opp. at 13 n.6. The Third Circuit's reasoning applies equally here, where the plaintiffs lack "any personal stake in the eventual outcome" because a third party has fully covered the cost of their claims. 620 F. App'x at 113.



“mulligan” and become personally responsible if a future claim were denied. P. Opp. at 7-11. Even assuming that plaintiffs continue to use TTFT, they will not suffer a future injury if their Medicare claims are approved, as they apparently have been recently under the 2019 LCD. *See* P. Opp. at 2 (“Other than the cases at issue, each of Plaintiffs’ claims has eventually been paid.”). Nor do plaintiffs assert that their future claims are likely to be denied.

In the hypothetical event that one of their future claims were denied, the plaintiffs speculate that an ALJ might hold them personally responsible under 42 U.S.C § 1395pp. Section 1395pp(b) states that “in the case of *comparable situations* arising thereafter with respect to such individual, [she] shall, by reason of such notice . . . be deemed to have knowledge that payment cannot be made for such items or services.” (emphasis added). However, there was a significant change between the 2014 LCD, which categorically denied coverage for TTFT, and the 2019 LCD, under which the plaintiffs’ recent TTFT claims have been approved. It is highly unlikely that an ALJ would deem the plaintiffs to have knowledge that their TTFT claims would be denied under the 2019 LCD, given a denial in different circumstances under the 2014 LCD. It is even more far-fetched to believe that the Secretary would hold the plaintiffs personally liable given that the decisions on appeal explicitly found that “[t]he Beneficiary neither knew, nor reasonably should have been expected to know, that any of the services would not be covered by Medicare.” AR at 839; *see also* AR at 109. And, even in the unlikely event that the plaintiffs were held personally liable, they could still appeal to federal court.

In sum, the plaintiffs’ future injury hypothesis reads as follows: *If* the plaintiffs continue to use TTFT, *if* Novocure requires the plaintiffs to sign an ABN (thereby shifting financial responsibility in the event of non-coverage), *if* the plaintiffs’ future claims are denied under the 2019 LCD, *if* the ALJs deem the plaintiffs to have knowledge that their claim would be denied,

and *if* the ALJs’ decisions are not changed on appeal, only then the plaintiffs would owe money out of pocket. Standing, however, cannot be premised on multiple contingencies—several of which are highly unlikely—that could ultimately result in an injury at some unknown point in the future. *See Reilly v. Ceridian Corp.*, 664 F.3d 38, 43 (3d Cir. 2011) (holding purported injury in fact was too conjectural where “we cannot now describe how Appellants will be injured in this case without beginning our explanation with the word ‘if’”); *see, e.g., Hull*, 66 F. Supp. 3d at 282-83 (finding that plaintiff’s potential liability under section 1395pp(b) was “wholly contingent upon the future acts or omissions of third parties” and failed to establish an impending injury); *Pehoviack*, 2020 WL 4810961, at \*5 (“Plaintiff argues . . . that she may be held personally liable for future treatments, or that her TTFT supplier might require her to sign an agreement assuming liability for the costs of future Medicare denials. None of these potential injuries, however, has come to pass; indeed, Plaintiff has received favorable Medicare decisions for treatment periods subsequent to the denial at issue here.”) (citation omitted); *Komatsu*, 2020 WL 5814116, at \*2 (same); *Cal. Clinical Laboratory Ass’n v. Secretary of HHS*, 104 F. Supp. 3d 66, 80 (D.D.C. 2015) (noting that plaintiff failed to allege that she “has received, or will receive, an advanced beneficiary notice that would make her—and not a provider—financially responsible for” future claims and finding that a “speculative chain of possibilities” regarding the potential for future claim denials was not an “impending” injury).<sup>6</sup>

In *Clapper*, the Supreme Court did not view much of a difference between requiring that an injury be “clearly impending” and that there be a “substantial risk” of injury. *See Clapper v.*

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<sup>6</sup> A case concerning the standing of environmental groups to challenge a plan to manage a forest is of no relevance here. *Jayne v. Sherman*, 706 F.3d 994, 1000 (9th Cir. 2013) (quoting *Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1516 (9th Cir.1992)); P. Opp. at 9. The plaintiffs also fail to meaningfully distinguish *California Clinical*, which also involved an allegation that future Medicare claims may be denied. P. Opp. at 14.

*Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013). As the Court noted, a plaintiff “bear[s] the burden of pleading and proving concrete facts showing that the defendant’s actual action has caused the substantial risk of harm.” *Id.* A plaintiff cannot “rely on speculation about the unfettered choices made by independent actors not before the court.” *Id.* (quotation marks omitted). Here, the plaintiffs do not show a “substantial risk” that the unfavorable decision on appeal will cause the loss of their “mulligan.” Rather, given the facts above, unlike in *Dep’t of Commerce v. N.Y.*, the plaintiffs’ do not show “the predictable effect of Government action on the decisions of third parties.” 139 S.Ct. 2551, 2566.<sup>7</sup> Instead, the plaintiffs’ arguments that they “may be held personally liable for the costs of future Medicare denials, or that [their] TTFT supplier might require [them] to sign an agreement assuming liability for the costs of future Medicare denials . . . are too speculative to establish standing.” *Prosser*, 2020 WL 6266040, at \*1. Accordingly, the plaintiffs’ “attenuated chain of inferences” does not suffice for Article III standing. *Clapper*, 568 U.S. at 414 n.5.

### **B. The Plaintiffs Cannot Satisfy the Other Elements of Standing.**

Because the plaintiffs do not address the other elements of standing, the Secretary’s motion to dismiss should be granted. D. MTD at 11-12.

## **III. CONCLUSION**

For the foregoing reasons, and because the plaintiffs’ lack of standing cannot be rectified by amending their Complaint, the Secretary respectfully requests that the Court grant his motion to dismiss for lack of subject-matter jurisdiction and dismiss the Complaint with prejudice.

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<sup>7</sup> Contrary to the plaintiffs’ opposition, at 10, *Commerce* did not modify the holding of *Clapper* but rather reiterated that “mere speculation” as to future injuries is insufficient. 139 S.Ct. at 2566.

Respectfully submitted,

WILLIAM M. McSWAIN  
United States Attorney

/s/ Veronica J. Finkelstein  
for Gregory B. David

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GREGORY B. DAVID  
Assistant United States Attorney  
Chief, Civil Division

/s/ Eric S. Wolfish

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ERIC S. WOLFISH  
Special Assistant United States Attorney/  
Assistant Regional Counsel, HHS  
[Eric.Wolfish@hhs.gov](mailto:Eric.Wolfish@hhs.gov)

/s/ Matthew E. K. Howatt

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MATTHEW E. K. HOWATT  
Assistant United States Attorney  
United States Attorney's Office  
615 Chestnut Street, Suite 1250  
Philadelphia, PA 19106  
Tel: 215-861-8335  
Fax: 215-861-8618  
[Matthew.Howatt@usdoj.gov](mailto:Matthew.Howatt@usdoj.gov)

Dated: December 10, 2020

**CERTIFICATE OF SERVICE**

I hereby certify that on this day, I caused a true and correct copy of the foregoing reply to be served on all counsel for all parties via the Court's CM/ECF system.

/s/ Matthew E. K. Howatt

MATTHEW E. K. HOWATT  
Assistant United States Attorney

Dated: December 10, 2020